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HUESCHEN AND SAGE

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Dated: 27 February 2009

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Serial No. : 10/578,765

Filed : March 20, 2007

Title : COMPOSITIONS COMPRISING CYCLOHEXYLAMINES AND AMINOADAMANTANES

Art Unit : 1614

Examiner : Timothy P. THOMAS, Esq.

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Honorable Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313

PETITION FOR WITHDRAWAL OF A PREMATURE FINAL REJECTION UNDER  
37 CFR § 1.181

Sir:

In accordance with MPEP § 1002.02(c), the Applicants respectfully hereby submit this Petition for withdrawal of a Premature Final Rejection.

On December 4, 2008, the Office issued an Office Action, **a Final Rejection**, wherein instant Claims 1, 4-5, and 39-41 remained rejected for obviousness under 35 USC § 103(a) based on the disclosure of the Parsons, et al. reference.

At page 4 of the instant Office Action, the Office states that no arguments rebutting this obviousness rejection were presented in the previous Response, and that, therefore, the rejection is maintained based on the reasons of record.

In the Response dated August 14, 2008, the Applicants stated the following with respect to the obviousness rejection (see page 5 of the Response):

The Applicants respectfully submit that there is no teaching in the Parsons, et al. disclosure to suggest the surprising/unexpected anti-microbial properties associated with neramexane, which properties are disclosed in the instant specification, for example, at pages 25-27. The specification also discloses (at page 16) that such properties provide advantages over conventional formulations in terms of tolerability and safety since the microbial quality of the composition is provided by the active ingredient itself. Therefore, in view of the surprising and unexpected effects associated with the instantly claimed compositions, the disclosure of the Parsons, et al. reference, alone or in combination with the disclosure of the Gupta, et al. reference does not render the instantly claimed **preservative free** compositions obvious.

The Applicants note that the Office acknowledges the above-mentioned argumentation with respect to the maintained combination rejection discussed at page 4 of the instant Office Action. Thus, the Applicants respectfully submit that the Office has clearly overlooked the fact that the argumentation rebutting the Parsons, et al. reference was directed to the rejection based on the disclosure of this reference **alone or in combination** with the Gupta, et al. reference. The Office's prejudicial refusal to consider this rebuttal, which was clearly of record in the last response, has necessitated the instant petition.

Moreover, Claims 1, 13, 26, and 44 also remain rejected for obviousness under 35 USC § 103(a) based on the disclosure of Parsons, et al. in view of Gupta, et al. (US Published Application No. 2005/0014743). As noted above, the Office acknowledges the previously submitted argumentation that there is no teaching in the Parsons, et al. reference to suggest the surprising/unexpected effects associated with neramexane; however, it is the position of the Office that the instant specification does not demonstrate such effects.

With respect to the relied upon disclosure at pages 25-27, it is the position of the Office that this disclosure is related to memantine mesylate rather than neramexane mesylate. The Office states "[a]pplicant is invited to provide evidence of unexpected results for neramexane mesylate, to demonstrate the position argued."

The Applicants respectfully reiterate that Example 4 at page 25 of the instant specification discloses that preservative free **neramexane mesylate** samples were prepared and then tested (according to the protocol described in Example 1) and that the results are shown in Tables 7-10 as well as the fact that "the results demonstrate that all tested solutions were microbiologically stable and effectively preserved against microbial contamination." The Applicants also note that the table headings for Tables 7-10 contain an obvious typographical error, referring to memantine rather than neramexane; however, the Applicants further submit that it would be clear to one of ordinary skill in the art, based on the description in Example 4, that the data in Tables 7-10 refer to neramexane mesylate formulations and not memantine mesylate formulations.

Moreover, Example 10 at pages 37-38 of the instant specification discloses data demonstrating the antibacterial effectiveness of preservative free neramexane oral solutions, which provision of unexpected results has always been of record in the instant application and which, it is assumed and expected that the Office consider.

Thus, the Applicants respectfully submit that the Office refusal to consider the previously submitted argumentation, which argumentation finds clear basis in the specification disclosure, is prejudicial to the Applicant.

In view of the foregoing, the Applicants respectfully request withdrawal of the Finality of the instant Office Action and, upon favorable review, reinstatement of non-final status should any insignificant obstacles to patentability remain.

Respectfully submitted,

THE FIRM OF HUESCHEN AND SAGE

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